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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/065,672	04/23/98	BILLING-MEDEL	6086.US.P1

023492

HM12/0814

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DEPT. 377 - AP6D-2

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EXAMINER

TURNER, S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/065,672

Applicant(s)

Billing-Medel

Examiner  
Sharon L. Turner, Ph.D.

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1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6-5-01
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-53 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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### **Response to Amendment**

1. The amendment filed 6-5-01 has been entered into the record and has been fully considered.
2. Claims 1-6, 11-12, 15 and 18-21 are canceled. Claims 22-53 are pending.
3. Applicant's remarks indicate that the examiner agreed that a forthcoming Declaration under 37 CFR 1.132 would be considered as timely filed. However, it is noted that no such Declaration has been received by the Office and thus cannot be considered timely or considered as to its merits. A declaration would have been considered only if submitted prior to the taking up of the action by the examiner for action.
4. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

### **Rejections**

#### ***Claim Rejections - 35 USC § 101 and 112***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 22-53 stand rejected under 35 U.S.C. 101 as set forth in Paper No. 12, mailed 12-1-00 and as set forth herein, because the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility.

Applicants argue that detection of the claimed sequences in normal and diseased prostate and detection of the claimed sequences outside host prostate tissues provides utility to the claimed sequences as a diagnostic, including over expression and as an indicator of treatment.

Applicant's arguments filed 6-5-01 have been fully considered but are not persuasive. In particular the examiner notes that the evidence of detection in both diseased, non-diseased and alternative tissues fails to indicate any particular condition, diagnosis, treatment or cell tissue type and thus it is unclear to the examiner how the instant sequences can be considered diagnostic. In addition, there is no evidence of over expression in any particular diseased state, condition, or that such can be used as a prognostic indicator in particular as no levels of such over expression appear to be indicated. Thus for the aforementioned reasons and a lack of evidence of such asserted utilities the rejection is maintained as previously set forth and now inclusive of sequences encoding epitopes which would not be useful for the same reasons of record and absent evidence that any particular epitope was diagnostic or prognostic of any disease or condition.

8. Claims 22-53 also stand rejected under 35 U.S.C. 112, first paragraph as set forth in Paper No. 12, mailed 12-1-00 and as set forth above. Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established

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utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9. Claims 22-28, 30, 36-38 and 40 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants previously amended the claims to recite nucleic acid sequences selected from the group consisting of position 4-269 of SEQ ID NO:2, positions 1-276 of SEQ ID NO:4 and positions 1-276 of SEQ ID NO:5. Such recitations have been added without identification of support in the specification as originally filed and no support for such recitations has been found by the examiner. Thus, such recitations constitute new matter.

Applicants argue that as the parent application contemplated fragments that instant claims to the specific fragments are supported.

Applicant's arguments filed 6-5-01 have been fully considered but are not persuasive. In particular the examiner notes that the parent application does not appear to contemplate the specific fragments which are less than the whole or a specific utility for the specified fragments as now recited and thus absent support the recitation constitutes new matter.

***Priority***

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10. Applicant's claim to priority under 35 USC 120 to patent application 08/838,968 is denied because applicant does not have support for 100% identity of SEQ ID Nos:1-5 and 12-14, see Figure 1. Thus the priority date awarded instant claims is the instant filing date, 4-23-98.

Applicants clarification of the discrepancies in sequence indicate that the invention was not perfected at the time of filing the provisional application. As a claim may only have a single priority date, the date of invention as directed to the recited SEQ ID NO's is the date of instant filing, 4-23-98. As the recited subject matter of the amended claims is also not supported by the priority application and constitutes new matter, the earliest possible date of invention is instant filing absent evidence of support.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 26, 28-29, 37-39 stand rejected as set forth in Paper Nos: 8 and 12 under 35 U.S.C. 103(a) as being unpatentable over any one of the following references; Genbank Accession No. AA631976, 31 October 1997, Genbank Accession No. N80180 4 April 1996 and Genbank Accession No. AA578209, 11 September 1997, in view of Sambrook et al, Molecular Cloning, 1989, 16.1-16.16.

Applicants argue that the claim amendments obviate the rejection.

Applicant's arguments filed 6-5-01 have been fully considered but they are not persuasive because the disclosed nucleic acids encode 6 amino acid epitopes in common, see previous alignments in particular.

### **Rejections Necessitated by Amendment**

#### ***Claim Objections***

13. Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 25 depends from claim 22 but broadens the nucleic acids to that of comprising language as the nucleic acid contains alternative sequences to the recited sequences "consisting of".

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14. Claims 25, 28-29, 34, 38-39, 44, 48 and 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The claims newly recite a "sequence encoding at least one epitope" absent evidentiary support for such recitation in the specification as originally filed. Applicant should point by page and line number where support may be found for such newly amended recitation.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 22-35, and 46-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While the skilled artisan recognized a degenerate codon sequence for an amino acid, one does not readily recognize one for a nucleic acid sequence which is the subject of instant claims as directed to nucleic acid sequences. Thus, the skilled artisan cannot readily discern that which is intended to be encompassed by degenerate codon equivalents of a nucleic acid sequence as recited in the claims.

***Claim Rejections - 35 USC § 102***

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --



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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 25, 28, 34, 38, 44, 48 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by GenEmbl Accession No. YSCNACT, 16 February 1996 and Lee et al., J. Biol. Chem., 264(21):12339-12343.

YSCNACT nucleotides 765-748 disclose nucleotides identical to nucleotides 168-185 of SEQ ID NO:1. In addition, YSCNACT nucleotides 765-748 disclose nucleotides identical to nucleotides 159-176 of SEQ ID NO:3. The sequences correspond to epitopes as the sequences are 18 base pairs in length and thus would be expected to encode a 6 amino acid epitope as claimed. The isolated clone is propagated in a transfected host cell. Thus the reference teachings anticipate the claimed invention.

19. Claims 28, 34, 38 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession Nos: T25848 and T25057 as disclosed in Matsubara et al., WO9514772, 1 June 1995, not included as the publication is in a foreign language and is over 2,000 pages in length. The Genbank Accessions are listed on the PTO-892 and are included herewith.

Matsubara et al., teach nucleotides 119-137 of SEQ ID NO:4 and 289-311 of SEQ ID NO:5. The nucleic acids are at least 18 base pairs in length and thus teach a 6 amino acid epitope of the disclosed sequences, see in particular alignments. Thus, the reference teachings anticipate the claimed invention.

### ***Status of Claims***

20. No claims are allowed.

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### Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
August 13, 2001

*Gary L. Kunz*  
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